



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-550]

Importer of Controlled Substances Application: Janssen Pharmaceuticals, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

In accordance with 21 CFR 1301.34(a), this is notice that on October 9, 2019, Janssen Pharmaceuticals, Inc., 1440 Olympic Drive, Athens, Georgia 30601-1645 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled Substance	Drug Code	Schedule
Thebaine	9333	II

Concentrate of Poppy Straw	9670	II
Tapentadol	9780	II

The company plans to import intermediate forms of tapentadol (9780) and thebaine (9333) for further manufacturing prior to distribution to its customers. The company plans to import concentrate of poppy straw (9670) to bulk manufacture other controlled substances. No other activity for these drug codes is authorized for this registration.

Dated: November 8, 2019.

William T. McDermott,
Assistant Administrator.

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